

Pharma Science, Inc.

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August 19, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, Maryland 20852

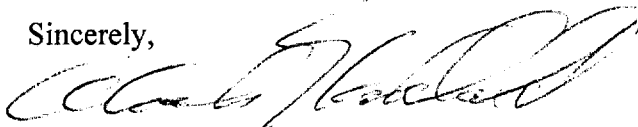
Re: Docket No. 99D-2249

Dear Sir or Madam:

The VICH Guideline for Stability Testing for Medicated Premixes specifies 40°C at 75% humidity. The upper temperature and humidity are not compatible with the traditional multi-wall bag used for the packaging of the medicated premix. The polyethylene layer is not continuous, causing the material to be exposed to the high moisture conditions affecting both the active and grain diluent material.

Since the proposed conditions far exceed any continuous environmental conditions of use, it is recommended that the temperature conditions be utilized with ambient conditions.

Sincerely,



Alexander MacDonald, PhD

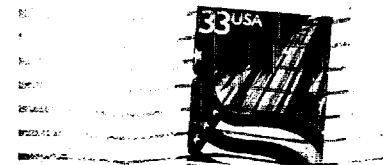
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